DEPARTMENT OF HEALTH & HUMAN SERVICES

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

WARNING LETTER
2001-DT-17

May 25, 2001

Mr. Ike Martin Ekwealor, President
M. E. Pharmaceuticals, Inc.
273 U.S. 35 Highway
Economy, IN 47339

Dear Mr. Ekwealor:

During an April 25-May 3, 2001 inspection of your manufacturing facility, which processes among other products prenatal prescription vitamins in tablet and capsule form, Investigator Jeffrey Sommers documented serious deviations from the Current Good Manufacturing Practice Regulations (CGMP - Title 21, Code of Federal Regulations, Parts 210 and 211). These deviations cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

1. Failure to establish a Quality Control Unit. [21CFR 211.22]
2. Failure to establish written procedures designed to assure that the drug products have the identity and strength they purport or are represented to possess. [21 CFR 211.100(a)]
3. Failure to establish master production and control records. [21 CFR 211.186]
4. Failure to establish adequate batch and control records for each batch of drug product produced, including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished. [21 CFR 211.188(b)]
5. Failure to maintain complete records of the periodic calibration of scales. [21 CFR 211.194(d)]
6. Failure to have written specifications, tests and/or release procedures for some components and finished drug products. [21 CFR 211.84, 211.160 and 211.165]
7. Failure to have an ongoing stability program to determine appropriate expiration dates. [21 CFR 211.166]

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts. Additionally, pending NDA, ANDA, or export approval requests may not be approved until the above violations are corrected. We request that you take prompt action to correct these deficiencies and to ensure that your drug processing operations are in full compliance with the Act and regulations promulgated thereunder. Failure to make prompt corrections may result in regulatory action without further notice, such as seizure and/

It is my understanding that you acknowledge that your firm was operating with serious Good Manufacturing Practice deficiencies and have voluntarily shut down operations until the firm is in substantial compliance. Investigator Sommers has provided you with a copy of 21 CFR parts 210 and 211.

Please notify this office in writing, within 15 working days of the receipt of this letter, of any additional steps you have taken to correct the noted violations including an explanation of each step being taken to prevent the recurrence of similar violations. If additional corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Any additional correspondence should be directed to the Food and Drug Administration, attention Mrs. Judith A. Putz, Compliance Officer at the above address.

Sincerely,

David M. Kaszubski

David M. Kaszubski
Acting District Director
Detroit District